

**STATEMENT OF DAVID CERTNER BEFORE THE IMPORTATION TASK
FORCE
CONSUMER STAKEHOLDER MEETING
MARCH 19, 2004**

Mr. Chairman and members of the task force, my name is David Certner, and I am the Director of Federal Affairs for AARP. AARP believes the enactment of last year's Medicare prescription drug law was a good first step in the effort to provide access to affordable prescription drugs to older Americans. However, more must be done to hold down the rising costs of prescription drugs. Importation is one important element in that effort.

The health and safety of individuals must remain paramount. But the viability and need for safe importation must be addressed within the context of two critical health concerns:

- ?? First, the health security of those who cannot afford and thus do not take the proper medication, and
- ?? Second, the large and growing number of Americans who are already traveling to Canada or purchasing drugs over the internet today, without any safety regime in place.

Importation Safety Issues

AARP supports importation from licensed Canadian pharmacies and wholesalers provided that certain safety features are in place. We are confident that drugs purchased from Canada can be as safe as drugs purchased in the U.S. However, we also know that supply can be limited to Canada, and thus many have proposed importation beyond Canada. Should legislation be enacted, or regulations promulgated, that would allow for the importation of drugs from other countries, AARP would like to see the following safeguards enacted:

FDA Certification

- ?? FDA will need the authority and resources to inspect pharmaceutical plants in foreign countries to ensure the plants conform to US safety standards. In some cases, specific plant lines of production can be certified in lieu of certifying the entire plant.

- ?? FDA should certify the safety of pharmaceuticals from these plants. For example, FDA should provide electronic links from its web site to approved internet pharmacies in Canada.
- Having the FDA web site as the point of contact for a list of approved pharmacies will provide consumers with an official, secure internet site for safe drugs.
 - Consumers without Internet access should be able to call a toll free number sponsored by the FDA or HHS in order to get information.
 - International pharmacies eligible to participate in importation activities must be fully accredited and licensed by a reputable licensing board.
- ?? There must be mechanisms in place to guarantee the quality of pharmaceutical dispensing and distribution. For example:
- Pharmaceuticals should be dispensed and distributed according to the usual and customary practice of the industry.
 - Consumer privacy should be protected.
 - Shipping and handling, processing fees, and other costs should be reasonable and fully disclosed to the consumer.

Pedigree Requirements

- ?? FDA will need the authority and resources to enforce pedigree requirements back to the point of manufacture. Initially these pedigree requirements should be either in paper or electronic form, although eventually paper should be phased out in favor of the electronic form.
- ?? FDA will need the authority and resources to inspect the flow of prescription drugs from the point of manufacture to the ultimate destination, both in instances of reported noncompliance, as well as on an annual basis, as needed.
- ?? Imported pharmaceuticals should be shipped in a manner that provides a tracking number (e.g., Federal Express, DHL, UPS, etc.) to reduce the opportunity for counterfeit pharmaceuticals to enter the stream of commerce from outside the point of manufacture.

Anti-tampering/anti-counterfeiting requirements

- ?? The FDA should consider prohibiting repackaging/relabeling of pharmaceuticals imported from other countries.
 - The FDA can enforce this requirement through its pedigree standards.
 - Labels for pharmaceuticals destined for the US should be written in English at the point of manufacture.
- ?? As the technology in this area progresses imported pharmaceuticals should be equipped with state of the art anti-tampering and anti-counterfeiting devices, such as bar codes, specialized ink, etc.

Other Issues

In addition, there are other issues the Task Force should consider:

- ?? While we need to ensure the safety of imported pharmaceuticals, there remains a strong need to examine the safety of pharmaceuticals within the United States drug supply in order to prevent counterfeit, diluted, or ineffective drugs.
- ?? Pharmacies should be subject to rigorous privacy standards to ensure the confidentiality of individuals' personal health information. U.S. privacy laws, such as HIPAA, may be unenforceable with respect to imported pharmaceuticals.
- ?? The FDA, or other U.S. entity, should assess the impact of regulated importation on the price and quality of pharmaceuticals worldwide.

Conclusion

In conclusion, we urge this task force to expedite its work, so that by mid-year we have the benefit of your efforts as legislation moves forward this year. It is important to keep in mind that our members are daily pressed by the high costs of prescription drugs. Many already have chosen to go to Canada, or to purchase their drugs through the internet. It is not simply a question of whether importation should be legal or not. The fact is that importation is happening today, and it is critical that we ensure that it is done under a regime that best ensures safety. Thus we urge the task force to address issues raised in this statement, as well as other measures to ensure safety, including such issues as:

- ?? What resources (human and financial) will FDA need to ensure safety?
- ?? Whether any imported drugs have different formulations than the US market?
- ?? How to ensure safety in plants that produce the same drug but use different standards based on where the drug is sold?

The American public, and our members, are demanding action on prescription drug costs. This task force, by addressing how best to ensure the safe importation of pharmaceuticals, has an opportunity to address this critical health care issue. We look forward to working with you to help Americans have greater access to affordable prescription drugs.